

Remarks

Claims 1-11 were previously pending in the subject application. By this Amendment, the applicants have amended claims 1, 2, and 6-11, and have added new claims 12-16. In addition, the applicants have amended the specification to correct an obvious typographical error.

Support for the amendments can be found throughout the application as originally filed. Specifically, support for the amendments to claims 1, 7, and 9-11 can be found at, for example, page 6, lines 8-17; support for the amendments to claims 2 and 8 can be found at, for example, page 6, lines 25-28; support for new claims 12 and 16 can be found at, for example, page 6, lines 17-25; support for new claims 13 and 14, which recite the weight percent of the proteins derived from cheese, can be found at, for example, page 7, lines 6-9; support for new claim 15 can be found at, for example, page 8, lines 4-6. No new matter has been introduced.

Accordingly, claims 1-16 are before the Examiner for further consideration. Favorable consideration of the claims now presented is earnestly solicited.

The amendments set forth herein should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

Claims 1-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Izvekova *et al.* The applicants respectfully traverse this rejection to the extent that it might be applied to the claims as amended herein.

The current invention provides an antibacterial composition that has unexpectedly high inhibitory effects against Gram-positive bacteria. The inhibitory effect against Gram-positive bacteria is achieved by an unexpected advantageous effect of a combination of factors, including the pH of 4.6 or less, the energy ratio of carbohydrates, proteins, and fats, and that the fermented dairy product is cheese.

The Izvekova *et al.* reference does not teach or suggest the antibacterial composition of the current invention. Specifically, while the Izvekova *et al.* reference broadly discloses that fermented

milk products are typically comprised of (wt. %) proteins of 0.35 – 34.0, fats of 0.05 – 36.0, and carbohydrates of 1.5 – 70.0 (column 5, lines 22-25), the reference does not teach or suggest a composition having the advantageous energy ratio of carbohydrates, proteins, and fats as claimed by the current applicants, *i.e.*, the energy ratio of carbohydrates, proteins, and fats being 50% to 70%, 4% to 25%, and 20% to 30%, respectively. As shown in Appendix A attached with the Response filed June 21, 2011, the energy ratio of carbohydrates, proteins, and fats of the compositions disclosed in Izvekova *et al.* reside outside of the ranges claimed by the current applicant.

Also, before optimization can be a relevant issue, a particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result. *In re Antonie*, 559 F.2d 618, 195 U.S.P.Q. 6 (C.C.P.A. 1977). Optimization of a parameter that is not recognized to be a result effective variable is an exception to the rule that it would be obvious for the skilled artisan to determine an optimum value within a disclosed range. *Id.*

In the current case, the Izvekova *et al.* reference does not teach or suggest that adjusting the energy ratio of carbohydrates, proteins, and fats would provide any advantageous effect. The Izvekova *et al.* reference also provides no suggestion of the claimed energy ratio. Further, the Izvekova *et al.* reference does not provide a person skilled in the art with any teaching that would lead to the specific energy ratio of carbohydrates, proteins, and fats as claimed by the current applicants.

In addition, the Izvekova *et al.* reference does not teach or suggest a composition that inhibits the proliferation of Gram-positive bacteria. One skilled in the art would not expect the fermented milk preparations disclosed in Izvekova *et al.* to have any significant antibacterial activity against Gram-positive bacteria.

As shown in the Expert Declaration of Dr. Hisae Kume filed November 1, 2010 (“the first Expert Declaration”) and the second Expert Declaration of Dr. Hisae Kume filed June 21, 2011 (“the second Expert Declaration”), acidic fermented milk preparations that do not have the currently-claimed energy ratio have little or no antibacterial activity against Gram-positive bacteria.

For instance, the L.A lactic acid bacteria beverages used in the experiments reported via the second Expert Declaration were prepared based on the fermented milk preparations disclosed by

Izvekova *et al.* Specifically, the LA lactic acid bacteria beverages were prepared by fermenting with a lactobacillus starter, and have the pH values and respective weight percentages of carbohydrates, proteins, and fats disclosed by Izvekova *et al.* (see pages 2-3 and Table 1 of the second Expert Declaration). The LA lactic acid bacteria beverages, however, do not have the energy ratio of carbohydrates, proteins, and fats as claimed in the current invention.

As shown in Figure 1 of the second Expert Declaration, the LA lactic acid bacteria beverages have little suppressive effect against the proliferation of Gram-positive bacteria. Specifically, the viable bacteria counts of MRSA contained in the 24-hour culture of the lactic acid bacteria beverages remained higher than  $10^5$  cfu/g.

The comparative data reported in the second Expert Declaration show that the antibacterial effect against Gram-positive bacteria results from the combined effect of the claimed pH value of 4.6 or less and the claimed energy ratio of carbohydrates, proteins, and fats. The fermented milk products disclosed by Izvekova *et al.*, which do not have the energy ratio of carbohydrates, proteins, and fats as claimed in the current invention, would not be expected to have significant antibacterial effect against Gram-positive bacteria.

Thus, the Izvekova *et al.* reference provides no teaching that would lead the skilled artisan to the composition claimed by the current applicants. Accordingly, no *prima facie* case of obviousness has been established.

Furthermore, a finding of obviousness can be rebutted by showing that the claimed invention exhibits one or more superior properties or advantages that a person of ordinary skill in the art would have found surprising or unexpected. *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1997).

The antibacterial composition of the current invention has unexpectedly superior antibacterial activity against Gram-positive bacteria, when compared to the fermented milk compositions disclosed by Izvekova *et al.* As noted above, the LA lactic acid bacteria beverages used in the experiments reported via the second Expert Declaration were prepared based on the fermented milk preparations disclosed by Izvekova *et al.* The LA lactic acid bacteria beverages, however, do not have the energy ratio of carbohydrates, proteins, and fats as claimed in the current invention.

As shown in Figure 1 of the second Expert Declaration, the viable bacteria count of MRSA contained in the 24-hour culture of the acidic liquid diet was 10 cfu/g or less, indicating that the bacterial count was lower than the detection limit. In contrast, the viable bacteria counts of MRSA contained in the 24-hour culture of the lactic acid bacteria beverages remained higher than  $10^5$  cfu/g.

The ability of the current invention to reduce viable MRSA counts below the detection limit and to a level that is several magnitudes lower than the viable MRSA counts contained in the lactic acid bacteria beverages (“the Izvekova *et al.* fermented milk preparations”) is a marked improvement that was entirely unexpected in view of the prior art.

Please note that the unexpected property, which is a property possessed by the claimed subject matter, need not be recited in the claims. see *In re Sullivan*, 498 F.3d 1345, 1353 (Fed. Cir. 2007), stating that “the issue here is not whether a claim recites a new use, but whether the subject matter of the claim possesses an unexpected use.”

In the current case, the current invention possesses an unexpected property – *i.e.*, the ability to reduce the viable bacteria counts of MRSA to less than 10 cfu/g. The unexpected property need not be recited in the claims.

In conclusion, the Izvekova *et al.* reference does not teach or suggest the following claim limitations: 1) the energy ratio of carbohydrates, proteins, and fats is 50% to 70%, 4% to 25%, and 20% to 30%, respectively; and 2) the composition has antibacterial effects against Gram-positive bacteria. Furthermore, the unexpectedly superior antibacterial activity against MRSA evidences that the applicants’ invention is not obvious. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) over Izvekova *et al.*

Claims 1-5 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jing (China Health Monthly, 8: 102-3, 2003). The applicants respectfully traverse this rejection to the extent that it might be applied to the claims as amended herein.

The Jing reference does not teach or suggest the current invention. Specifically, the Jing reference is directed to yogurt, and does not teach or suggest the currently-claimed composition that comprises cheese.

In addition, the Jing reference does not teach or suggest the current composition that has the energy ratio of carbohydrates, proteins, and fats being 50% to 70%, 4% to 25%, and 20% to 30%, respectively. Instead, as shown in Table A below, the energy ratio of the yogurt disclosed in the Jing reference is outside of the scope of the current applicants' claim 1.

Table A. Comparison of the Energy Ratio of Carbohydrates, Proteins, and Fats of the Jing's Yogurt Composition and the Current Invention

	Weight Percent of Jing's Yogurt	Energy Ratio of Jing's Yogurt	The Energy Ratio of Claim 1
Proteins	2.5g	13.89%	4% to 25%
Fats	2.7g	33.75%	20% to 30%
Carbohydrates	9.3g	51%	50% to 70%

Also, as discussed above, a particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 U.S.P.Q. 6 (C.C.P.A. 1977).

The Jing reference does not teach or suggest that adjusting the energy ratio of carbohydrates, proteins, and fats would provide any advantageous effect. The Jing reference also provides no suggestion of the applicants' claimed energy ratio. In addition, the Jing reference is directed to yogurt, whereas the current invention is directed to a composition that comprises cheese. A person skilled in the art would have no reason to arrive at the specific energy ratio of carbohydrates, proteins, and fats as currently claimed, based on the disclosures of Jing.

In addition, the Jing reference does not teach or suggest a composition that inhibits the proliferation of Gram-positive bacteria. The bacteria mentioned in the Jing reference are *E. coli* – Gram-negative bacteria (see page 2, line 26 of the English translation of Jing).

As shown in the second Expert Declaration, yogurt that does not have the claimed energy ratio of carbohydrates, proteins, and fats has little suppressive effects against Gram-positive bacteria. The Jing reference relates to nutritional benefits of yogurt products sold in China, including yogurt products manufactured by the Bright Dairy & Food Co. and other manufacturers (see page 1, line 5 of the English translation of Jing and the picture at page 102 of the original Jing reference (Chinese)).

Yogurts 1 and 2 used in the comparative experiments reported via the first Expert Declaration were manufactured by the same manufacturers described by Jing. Specifically, Yogurt 1 was manufactured by the Bright Dairy & Food Co. (Table 2 of the first Expert Declaration), and Yogurt 2 was manufactured by another major Chinese dairy manufacturer – China Mengniu Dairy Company. As with the yogurt products disclosed in Jing, Yogurts 1 and 2 have respective energy ratios of carbohydrates, proteins, and fats that are outside the scope of the applicants' claims. Thus, Yogurt 1 and Yogurt 2 do not deviate from the yogurt products described by Jing in any material aspect.

As shown in Figure 1 of the first Expert Declaration, Yogurt 1 and Yogurt 2 have little suppressive effect against the proliferation of Gram-positive bacteria. Specifically, the viable bacteria counts of MRSA contained in the 24-hour culture of the Yogurt 1 and Yogurt 2 were still  $10^6$  cfu/g or higher. Also, as shown in Figure 1 of the second Expert Declaration, another yogurt preparation (*i.e.*, Bulgaria Yogurt) also has little suppressive effects against Gram-positive bacteria.

Thus, the Jing reference does not teach or suggest a composition that inhibits the proliferation of Gram-positive bacteria. Also, one skilled in the art would not have expected that the yogurt products disclosed by Jing would have any anti-Gram-positive bacterial effects.

Furthermore, a finding of obviousness can be rebutted by showing that the claimed invention exhibits one or more superior properties or advantages that a person of ordinary skill in the art would have found surprising or unexpected. *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1997).

As noted above, as shown in Figure 1 of the first Expert Declaration, the viable bacteria counts of MRSA contained in the 24-hour culture of the acidic liquid diet was 10 cfu/g or less, indicating that the bacterial count was lower than the detection limit. In contrast, the viable bacteria counts of MRSA contained in the 24-hour culture of the Yogurt 1 and Yogurt 2 were still  $10^6$  cfu/g

or higher. The ability of the current invention to reduce viable MRSA counts below the detection limit and to a level that is several magnitudes lower than the viable MRSA counts contained in Yogurt 1 and Yogurt 2 (“yogurt products disclosed in Jing”) is a marked improvement, and would not have been expected by those skilled in the art.

In conclusion, the Jing reference does not teach or suggest the following limitations: 1) the composition comprises cheese; 2) the energy ratio of carbohydrates, proteins, and fats is 50% to 70%, 4% to 25%, and 20% to 30%, respectively; and 3) the composition has antibacterial effects against Gram-positive bacteria. Furthermore, the unexpectedly superior antibacterial activity against MRSA provides further evidence that the applicants’ invention is not obvious. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) over Jing.

Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Jing as applied to claims 1-5 above, and further in view of Izvekova *et al.* The applicants respectfully traverse this rejection to the extent that it might be applied to the claims as amended herein.

The deficiencies of the Jing and Izvekova *et al.* references are discussed above. The references, taken either alone or in combination, do not teach or suggest any composition having the advantageous energy ratio of carbohydrates, proteins, and fats as claimed in the current invention. In addition, the references do not teach or suggest any composition that has an antibacterial effect against Gram-positive bacteria. Further, the unexpectedly superior antibacterial effect against MRSA provides further evidence that the applicants’ invention is not obvious. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Claims 7-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jing and further in view of Egli *et al.* (U.S. Patent No. 3,932,680). The applicants respectfully traverse this rejection to the extent that it might be applied to the claims as amended herein.

The shortcomings of the Jing reference are discussed above. The Egli reference does not cure the deficiencies of the Jing reference. Specifically, the Egli reference is directed to methods of making yogurt, and does not teach or suggest the current invention that is directed to a method of

making an antibacterial composition that comprises cheese. Egli also does not teach or suggest any method for preparing a composition that has the claimed energy ratio of carbohydrates, proteins, and fats, or has antibacterial effects against Gram-positive bacteria.

With regard to claims 9 and 10, the cited references also do not teach or suggest that proteins derived from cheese account for 30 weight % or more of the proteins in the composition (claim 9) or 70 weight % or more of the proteins in the composition (claim 10).

Thus, the references, even when combined, do not teach or suggest claims 7-11. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Request for Continued Examination